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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/487,355 06/07/95 BOLOGNESI

D 7872-027

EXAMINER

18N2/1112

LAURA A CORUZZI
PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

STUCKER, J
ART UNIT PAPER NUMBER

1818
DATE MAILED:

15
11/12/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 7/28/97
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 16-19 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s) Decision on paper petition

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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This Office Action is in response to the amendment filed 7/28/97. Claim 9 has been canceled and claims 16-19 are added. Claims 16-19 are under final rejection.

Please note the attached response to the petition filed under 37 CFR §1.48(b).

The rejection of claim 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicant's arguments.

The rejection of claim 9 under 35 U.S.C. 112, first paragraph, **is withdrawn** in view of the cancellation of the claim. New enablement and scope of enablement rejections have been necessitated by amendment. Applicant's arguments have been considered in writing the new rejections in as much as they apply to the new rejections.

The provisional rejection of claim 9 under 35 U.S.C. 101 as claiming the same invention as that of claims 9-15 of copending Application No. 08/470896 **is withdrawn** as the subject matter in the amended claims in both cases does not now overlap.

The following are new objections and grounds of rejection necessitated by applicant's amendment.

The abstract of the disclosure is objected to because it does not accurately describe the claimed invention. Correction is required. See MPEP § 608.01(b).

Claims 16-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 18 are vague and indefinite in that it is unclear what is meant by "recognized". The claim would be more clear the claim were changed to include specific method steps, e.g., ...comprising identifying a [HBV] peptide by [search motifs] and contacting the cell with an effective concentration of said peptide for an effective period of time...."

Claims 17 and 19 should have the sequence ID numbers included.

Claims 16-19 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art

to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has shown in the specification that some specific peptides from a few examples can have some effect. This cannot be extended broadly to any peptide from any virus. The mechanism of infection from each of the many possible viruses that can be included in the search motif is so broad that one would have to engage in an undue amount of experimentation to find particular peptides from particular viruses that would have the desired effect. There is no guidance in the specification as to which proteins or peptides that are included in the immense number of peptides which fall within the search motifs that would inhibit viral infection. This is particularly true as each virus is different and would have a different mode of infection. A showing of the effectiveness of some peptides from HIV, for example, would not be a suitable showing of efficacy for hypothetical peptides from hepatitis B virus. The mode of action of the peptides is by applicant's own admission not known, and would therefore, exclude an expectation of success based on even a hypothetical mode of action. Each of the viruses in the specification are different from each other, have different routes of infection, different phylogenies, etc. Further, the specification teaches on page 340, lines 7-13 that "the antiviral activity of the peptides of the

invention may show a pronounced type and subtype specificity, i.e., specific peptides may be effective in inhibiting the activity of only specific viruses." One would not expect the instant method to transfer from one virus to another absent some working examples of peptides from the claimed virus. Therefore, the instant specification does not provide an enabling disclosure for the invention as claimed.

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting cell fusion, does not reasonably provide enablement for "inhibiting transmission" or "neutralizing hepatitis B virus". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Assuming *arguendo* that one would expect a given hepatitis B peptide to have an antiviral effect, the specification is not enabled for methods for "inhibiting transmission" or "neutralizing hepatitis B virus". The only disclosed antiviral activity taught in the specification is for inhibiting cell fusion between uninfected and infected cells *in vitro* by direct treatment with a peptide. The mode of action of the peptides in the instant method is unknown. One can not say with confidence that the peptides can

"neutralize" a virus or "inhibit" the transmission of the virus. The claim language implies specific direct activity against the virus. The only teaching in the specification at best is inhibition of cell fusion.

The specification, while enabled for *in vitro* methods, is not enabled for *in vivo* methods even if one were to have an expectation of success that a given hepatitis B peptide will have an antiviral effect. The specification teaches the use of some peptides in a static *in vitro* system while providing no guidance for using the claimed method in a dynamic *in vitro* system. A living body is extremely complex and unpredictable. Therefore, the instantly disclosed invention is not enabled for *in vivo* uses. Further, the specification is not enabled for antiviral activity by inducing an immune response. There is no evidence that an immune response, if induced would have an antiviral effect. The specification teaches use of peptides, not anti-peptide antibodies which are several steps removed from the peptides themselves. Thus, the instant specification is not enabled for the scope of the claimed invention.

The instant invention appears to be free of the prior art.

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No claims are allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 180 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 305-7939.

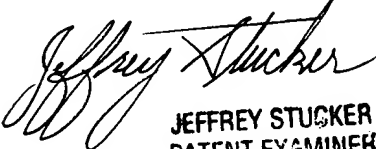
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Adams, Ph.D., can be reached on (703) 308-0570.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JEFFREY STUCKER
PATENT EXAMINER
GROUP 1800